PCT/EP2003/013995

Translation

PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference P166302PC-RE	FOR FURTHER ACTION	See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)
International application No. PCT/EP2003/013995	International filing date (*day/month/year*) 09 December 2003 (09.12.2003)	Priority date (*day/month/year*) 10 December 2002 (10.12.2002)
International Patent Classification (IPC) or national classification and IPC A61B 10/00		
Applicant UNIVERSITÄTSKLINIKUM CHARITÉ		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of 7 sheets, including this cover sheet.

   ☒ This report is also accompanied by ANNEXES, i.e., sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

   These annexes consist of a total of 7 sheets.

3. This report contains indications relating to the following items:

   - I ☒ Basis of the report
   - II ☐ Priority
   - III ☒ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
   - IV ☐ Lack of unity of invention
   - V ☒ Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
   - VI ☐ Certain documents cited
   - VII ☐ Certain defects in the international application
   - VIII ☐ Certain observations on the international application

Date of submission of the demand	Date of completion of this report
18 June 2004 (18.06.2004)	27 April 2005 (27.04.2005)
Name and mailing address of the IPEA/EP Facsimile No.	Authorized officer Telephone No.

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.
PCT/EP2003/013995

I. Basis of the report

1. With regard to the elements of the international application:*

☐ the international application as originally filed

☒ the description:
pages 1, 2, 6-11, as originally filed
pages _____, filed with the demand
pages 3-5, 5a, filed with the letter of 23 March 2005 (23.03.2005)

☒ the claims:
pages _____, as originally filed
pages _____, as amended (together with any statement under Article 19
pages _____, filed with the demand
pages 1-12, filed with the letter of 23 March 2005 (23.03.2005)

☒ the drawings:
pages 1/4-4/4, as originally filed
pages _____, filed with the demand
pages _____, filed with the letter of _____

☐ the sequence listing part of the description:
pages _____, as originally filed
pages _____, filed with the demand
pages _____, filed with the letter of _____

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.
These elements were available or furnished to this Authority in the following language _____ which is:

☐ the language of a translation furnished for the purposes of international search (under Rule 23.1(b)).

☐ the language of publication of the international application (under Rule 48.3(b)).

☐ the language of the translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

☐ contained in the international application in written form.

☐ filed together with the international application in computer readable form.

☐ furnished subsequently to this Authority in written form.

☐ furnished subsequently to this Authority in computer readable form.

☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.

☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. ☐ The amendments have resulted in the cancellation of:

☐ the description, pages _____

☐ the claims, Nos. _____

☐ the drawings, sheets/fig _____

5. ☒ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).**

** Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rule 70.16 and 70.17).*

*** Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.*

III. Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

1. The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non obvious), or to be industrially applicable have not been examined in respect of:

☐ the entire international application.

☒ claims Nos. 9-11

because:

☐ the said international application, or the said claims Nos. _____ relate to the following subject matter which does not require an international preliminary examination *(specify)*:

☐ the description, claims or drawings *(indicate particular elements below)* or said claims Nos. _____ are so unclear that no meaningful opinion could be formed *(specify)*:

☐ the claims, or said claims Nos. _____ are so inadequately supported by the description that no meaningful opinion could be formed.

☒ no international search report has been established for said claims Nos. 9-11.

2. A meaningful international preliminary examination cannot be carried out due to the failure of the nucleotide and/or amino acid sequence listing to comply with the standard provided for in Annex C of the Administrative Instructions:

☐ the written form has not been furnished or does not comply with the standard.

☐ the computer readable form has not been furnished or does not comply with the standard.

I. **Basis of the report**

1. This report has been drawn on the basis of *(Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to the report since they do not contain amendments.)*:

1 The amendments submitted by the applicant with the letter of 23 March 2005 introduce substantive matter which, contrary to PCT Article 34(2)(b), goes beyond the disclosure in the international application as filed.

Claim 1 relates to an optical biopsy instrument comprising a cannula and an endoscope. However, as per the amendments, the outer diameter of the endoscope and the inner diameter of the cannula are sized relative to one another so as to enable the endoscope to co-operate with the opening of the cannula to separate a tissue sample.
Consequently, a plurality of instruments which are not disclosed in the description are also claimed. For example, any endoscope in which the diameter of the cannula is smaller and the cannula is close enough to bring about a cutting effect is covered by the wording of claim 1.
In addition, this wording also covers an instrument containing an endoscope surrounded by a cutting tube and a cannula without a cutting edge, or an endoscope whose actuation is followed merely by the actuation of another cutting device.
Since the remaining claims likewise contain these amendments, their scope of protection is also extended.

The present report has been drawn up as if these amendments had not been carried out (PCT Rule 70.2(c). Consequently, the statement made below

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.
PCT/EP 03/13995

I. Basis of the report

1. This report has been drawn on the basis of *(Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to the report since they do not contain amendments.)*:

relates to:

Claims:

1: submitted on 18 June 2004 with the letter of 18 June 2004

2-11: original version.

Supplemental Box
(To be used when the space in any of the preceding boxes is not sufficient)

Continuation of: III

This report does not provide a reasoned statement concerning the novelty, inventive step, and industrial applicability of claims 9 to 11, because said claims relate to a surgical method and therefore were not searched (PCT Rule 39.1(iv)).

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims	7-8 (original version)	YES
	Claims	1-6 (claim 1 of 18.06.2004, claims 2-6 original version)	NO
Inventive step (IS)	Claims	-	YES
	Claims	1-8	NO
Industrial applicability (IA)	Claims	1-8	YES
	Claims	-	NO

2. Citations and explanations

2 Reference is made to the following documents:

D1: US-A-5 681 277
D2: US-A-4 620 547

3 **Novelty of independent claim 1 (PCT Article 33(1) and (2))**

3.1 D1 describes an optical biopsy instrument (see title of D1) comprising:
(a) a cylindrical cannula (figure 1: catheter 2) with a proximal end and a distal end (figure 8: tip 106), the cannula having a lateral opening (lateral depression 108)
(b) an endoscope (fibre optic 114) that is axially displaceable within the cannula.

The expression "an opening designed for receiving and separating a tissue sample" does not describe a technical feature, but only a characteristic of the opening. The device of D1 also enables a cutting device to be passed through one of the lumina (for example, figure 10 stylet lumina 140), and thus to carry out a receiving and separating in the region

of the opening. In this sense, it is designed "for receiving and separating a tissue sample".

3.2 The present application therefore does not meet the requirements of PCT Article 33(1), because the subject matter of claim 1 is not novel (PCT Article 33(2)).

3.3 Furthermore, the subject matter of claim 1 is not novel (PCT Article 33(2)) over D2. D2 discloses in figure 2 an optical biopsy instrument (see title of D2) comprising:
(a) a cylindrical cannula (outer shaft 1) with a proximal end and a distal end, the cannula having a lateral opening (2) designed for receiving and separating a tissue sample
(b) an endoscope (optical system 7) that is axially displaceable within the cannula.

4 Novelty of claims 2 to 6 and 8 (PCT Article 33(1) and (2))

4.1 Claims 2 to 4: the opening of the device in D2 has a cutting region (cutting edge 3). An edged section is thus implicitly disclosed, since only in this way can the opening be effective as a cutting region. Moreover, it is obvious for a person skilled in the art to provide serrations.
The opening is square in form. Other forms are obvious amendments of the design which are evident to a person skilled in the art.

4.2 Claim 5: in D1 and D2, the distal end is closed. Features which follow the words "in particular" do not bring about any restriction of the scope of

protection.

4.3 Claim 6: the words "slightly smaller" can be interpreted broadly and are unclear. The diameter of the endoscope can always be deemed "slightly smaller" than that of the cannula.

4.4 Claim 8: D1 discloses a glass fibre endoscope (fiber optics 114).
Moreover, a person skilled in the art would use the solution with the device of D2 to make the structure of the endoscope more flexible, simpler, and more robust. The subject matter of the claim therefore does not involve an inventive step (PCT Article 33(3)) either.

5 Inventive step of claim 7 (PCT Article 33(1) and (3))

5.1 It is obvious to a person skilled in the art to adapt the outer diameter of the cannula to the region of use, in other words to provide for smaller than 1.2 mm if the intention is to examine the nose or the milk glands.

The subject matter of claim 7 therefore does not involve an inventive step (PCT Article 33(3)).